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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/524,152 | 08/24/2005 | Beatriz Perez Esteban | 4126-4025 | 1501 |
| 27123 | 7590 | 09/25/2006 | EXAMINER | |
| MORGAN & FINNEGAN, L.L.P. 3 WORLD FINANCIAL CENTER NEW YORK, NY 10281-2101 | | | MONSHIPOURI, MARYAM | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1653 | |

DATE MAILED: 09/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/524,152 | Applicant(s) ESTEBAN ET AL. | |
| | Examiner Maryam Monshipouri | Art Unit 1653 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date ____ | 6) <input checked="" type="checkbox"/> Other: <u>see attachment</u> |

DETAILED ACTION

Claims 1-12 are under examination on the merits.

Claim Objections

Claims 1-7 are objected to because of the following informalities: Said claims recite the term "hybridising" in English rather than American. Since the instant patent application is an American Application it is requested to substitute said term with "hybridizing". Appropriate correction is required.

Priority

It is noted that applicant has claimed and is entitled to foreign priority, However the certified copies of foreign patent is not currently of record. Applicant is requested to possibly provide a copy of certified foreign patent to which priority is claimed, in response to this office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Said claim depends from itself.

Claims 1-8, 10-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "stringent conditions" in claim 1 (and its

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dependent claims 2, and 10-12), claims 4, 5, 6, and 7 is unclear. Applicant has provided some examples of hybridizing conditions in page 5 of the disclosure but has failed to provide a specific definition for said term. In the absence of a specific definition for said term the skilled artisan does not know which salt and temperature conditions to use in order to obtain claimed polynucleotides.

Claims 2-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear as to what is a fragment of fragment of polynucleotide of claim 1(a) in dependent claims 2-7.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated polynucleotide consisting of or comprising SEQ ID NO:1, does not reasonably provide enablement for any of the following:

(a) variants or fragments of SEQ ID NO:1 with no function and bacteria comprising said products (see claim 1, 11-12).

(b) 50%-97% homologs of SEQ ID NO:1 with no function and bacteria comprising said products (see claim 1, 7, 11-12).

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(c) nucleotides that hybridize to SEQ ID NO:1, fragments, homologs and variants thereof under "stringent conditions" with no function and bacteria comprising said products (see claim 1, 11-12) .

(d) probes comprising at least 5 or more contiguous nucleotides of SEQ ID NO:1, fragments, variants and homologs thereof with no function (see claim 8) .

(e) a recombinant DNA comprising or consisting of any polynucleotides listed as (a)-(d) above with no function (see claim 10) .

The criteria for undue experimentation, summarized in *re Wands*, 8, USPQ2n 1400 (Fed. Cir. 1988) are: 1) the quantity of experimentation necessary, 2) the amount of direction or guidance presented, 3) the presence and absence of working examples, 4) the nature of the invention, 5) the state of prior art, 6) the relative skill of those in the art, 7) the predictability or unpredictability of the art, and 8) the breadth of the claims.

The disclosure fails to teach which residues of SEQ ID NO:1 must be retained in products listed as (a)-(e) above such that said products retain 16S ribosomal RNA function. No examples of such residues are provided either. Current state of prior art indicates that once more than 5-6 bases of a DNA sequences encoding a full-length polypeptide is substituted, deleted, inserted etc. said variant is not longer necessarily capable of encoding a product with the same function as said full-length polypeptide(or more specifically is no longer capable of localizing bacteria which associate with *E. turbinata*).

Therefore, due to lack of sufficient guidance and examples provided and due to unpredictably of the prior art as to which residues of SEQ ID NO:2 are in charge of

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assigning function to its expression product one of skill in the art has to go through the burden of undue experimentation in order to screen for those products that retain full-length 16S ribosomal expression product function (i.e. localization of bacteria which associate with *E. turbinata*) and as such the claims go beyond the scope of the disclosure.

Since products of claim 1 are not enabled bacteria comprising them (claims 11-12) are not enabled either.

Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1 (and its dependent claims 4-7 and 11) claim 8 (and its dependent claim 9) and claim 10 are directed to the following **genera** of products which are merely defined by structure.

(a) a **genus** of variants or fragments of SEQ ID NO:1 with no function and bacteria comprising said products (see claim 1, 11-12).

(b) a **genus** of 50%-97% homologs of SEQ ID NO:1 with no function and bacteria comprising said products (see claim 1, 7, 11-12).

(c) a **genus** nucleotides that hybridize to SEQ ID NO:1, fragments, homologs and variants thereof under "stringent conditions" with no function and bacteria comprising said products (see claim 1, 11-12) .

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(d) a **genus** probes comprising at least 5 or more contiguous nucleotides of SEQ ID NO:1, fragments, variants and homologs thereof with no function (see claim 8) .

(e) a **genus** of recombinant DNA comprising or consisting of any polynucleotides listed as (a)-(d) above with no function (see claim 10) .

The specification does not contain any disclosure of the function of all DNA sequences listed as (a)-(e) above. The genera of cDNAs that comprise these above cDNA molecules is a large variable genera with the potentiality of encoding many different proteins or localizing many different symbiotic bacteria. Therefore, many functionally unrelated DNAs are encompassed within the scope of these claims, including partial DNA sequences. The specification discloses only a **single species** of each claimed genus (namely SEQ ID NO:1) which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised interim guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Moss et al. (Database Geneml, Accession No.AY054370 submitted 30, Aug 2001). Moss teaches an isolated recombinant polynucleotide sequence that has 100% identity to SEQ ID NO:1 of this invention, anticipating claims 1-7 and 10 and its sequence does comprise of more than 30 contiguous nucleotides of SEQ ID NO:1, anticipating claims 8-9. Moss also teaches that *Ecteinascidia turbinata* is the specific host of said sequence. Since said sequence is not endogenous to said host it follows that said sequence must originate from an outside invading bacterial source which by inherency is *Candidatus Endoecteinascidia frumentensis*, anticipating claims 11-12 of this invention.

Claims 1, 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Mabilat et al. (U.S. Patent No. 5,976,791, 11/1999). Mabilat teaches a polynucleotide sequence (see SEQ ID NO:53 in the attached sequence alignment) that displays 66.2% identity to SEQ ID NO:1 of this invention, anticipating claim 1 and 10). Mabilat's sequences does comprise more than 30 contiguous bases of SEQ ID NO:1, anticipating claims 8-9.

No claims is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571) 272-0932. The examiner can normally be reached on 7:00 a.m to 4:30 p.m. except for alternate Mondays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weber Jon P. can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

~~M. Monshipouri~~

Maryam Monshipouri Ph.D.

Primary Examiner
